

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO: WAVE 1 CASES ON ATTACHED EXHIBIT A	

**RESPONSE TO PLAINTIFFS' MOTION TO EXCLUDE
THE OPINIONS AND TESTIMONY OF STANLEY ZASLAU, M.D.**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") hereby respond in opposition to "Plaintiffs' Motion to Exclude the Opinions and Testimony of Stanley Zaslau, M.D." [ECF No. 2026] and "Memorandum in Support of Plaintiff's Motion to Exclude Certain Opinions of Dr. Stanley Zaslau" [ECF No. 2030] (collectively, the "Motion") as follows:

Dr. Stanley Zaslau is a board-certified urologist with two decades of experience treating women for stress urinary incontinence using TVT and TVT-O. Plaintiffs challenge several of Dr. Zaslau's opinions as being beyond the scope of his qualifications or unreliable. However, all of the opinions that Dr. Zaslau intends to offer at trial are well within the scope of his expertise and based on reliable methodology, including his own extensive experience and his review of peer-reviewed literature. For these reasons, Plaintiffs' Motion should be denied

BACKGROUND

Dr. Stanley Zaslau, MD, is a professor and Chief of the Division of Urology at West Virginia University. Mot. Ex. B, Zaslau *Hendrix* Report at 3. He is a medical doctor with a

specialty in urological surgery and is the first physician in the State of West Virginia to receive a subspecialty in Female Pelvic Medicine and Reconstructive Surgery. *Id.* He learned to perform the retropubic TVT procedure in residency (1996–2000) and has, in the years since, “performed hundreds of TVT and TVT-O procedures.” *Id.* at 2–4. Working together, he and his partner have “removed probably close to 200 patients’ mesh since we started counting them.” Mot. Ex. C, Zaslau 3/17/16 Dep. Tr., 48:8–23. Dr. Zaslau’s opinions contained in his expert reports were based on his “education, training, experience, professional society guidelines, analyses, position statements, and literature, the medical literature, TVT documents, depositions and other materials [he] ha[s] reviewed.” Mot. Ex. B, Zaslau *Hendrix* Report at 2; Resp. Ex. A, Zaslau *Guinn* Report.

ARGUMENT

I. Dr. Zaslau’s Opinions on Particle Loss and Fraying Are Reliably Based on His Experience and Review of the Literature.

Plaintiffs challenge Dr. Zaslau’s statement in his report that he has “not removed degraded particles of mesh or seen grossly altered structure of the knitting in any of” the mesh specimens he has removed during urethrolisis. Pls.’ Mem. [ECF No. 2030] at 3 (quoting Mot. Ex. B, Zaslau *Hendrix* Report 9). Plaintiffs say that this “essentially” amounts to saying “‘I have not seen it, so it does not happen.’” *Id.* This is, however, untrue. Dr. Zaslau’s statement does not suggest that the absence of degraded particles in meshes Dr. Zaslau has seen is evidence that such particles are absent in all cases. Instead, his statement is just part of his basis for his opinion that there is no clinically significant difference between machine-cut mesh and laser-cut mesh. Mot. Ex. B, Zaslau *Hendrix* Report 9. This opinion was based not just on his personal experience, but also on a review of peer-reviewed medical literature. *Id.*

Further, Dr. Zaslau's opinions on this topic are not contradicted by scientific literature or by internal Ethicon documents. During his deposition, Dr. Zaslau agreed with medical literature that showed that "particles that are of a foreign body cause a foreign-body response." Mot. Ex. D, Zaslau 3/17/16 Dep. Tr. 104:11–105:9. However, Dr. Zaslau clearly opined, based both on his personal experience and his review of peer-reviewed literature, that this foreign body response was not clinically significant. *Id.* at 104:3–10; Mot. Ex. B, Zaslau *Hendrix* Report 9; Resp. Ex. A, Zaslau *Guinn* Report 26. The literature plainly recognizes that some foreign-body responses are *subclinical*. See, e.g., Resp. Ex. B, Abstract, Xue et al., "Local foreign-body reaction to commercial biodegradable implants: an in vivo animal study," *Craniofacial Trauma Reconstr.* 2014 Mar;7(1):27-34. doi: 10.1055/s-0033-1364199, Epub 2014 Jan 9 ("All local foreign-body reactions were subclinical with no corresponding tissue swelling requiring drainage."). It may be that others have observed to the contrary, but that fact does not render Dr. Zaslau's opinions unreliable or irrelevant.¹

Further, Dr. Zaslau is *not* denying the observations or the opinions of others. He is, rather, asserting an opinion based on what he has learned through more than 15 years of clinical experience, professional presentations, and review of medical literature. See Mot. Ex. C, Zaslau 3/17/16 Dep. Tr. 138:1–22 (discussing that he has not observed a clinical difference between laser-cut and machine-cut mesh in his 15 years of professional experience or at presentations at

¹ The role of so-called "negative evidence" is well-recognized:

The probative force of negative testimony depends largely upon circumstances. In some circumstances, its probative force may be so slight as to reach the vanishing point; in other circumstances, such testimony may be more persuasive than the positive testimony of some witnesses. It is only when it is so clear that such testimony has no probative value whatever that reasonable men would not differ in their conclusions with reference thereto that courts are justified in disregarding it on the ground that it does not rise to the dignity of evidence.

Union Pac. R. Co. v. Burnham, 124 F.2d 500, 502 (10th Cir. 1941).

professional meetings); Resp. Ex. A, Zaslau *Guinn* Report 26 (“I have not seen any complications attributed to particle loss or mesh fraying in the hundreds of randomized controlled trials evaluating the safety and efficacy of TVT and TVT-O, nor have I had any problems or complications associated with particle loss from TVT-O in my practice.”). Just because Plaintiffs or their experts may disagree with Dr. Zaslau’s conclusions on this topic does not render his opinions unreliable. *See, e.g., In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 635 (S.D. W. Va. 2013) (“[E]xperts can disagree on their opinions and conclusions, as long as they are based on reliable principles and methods.”).

II. Dr. Zaslau’s Sheath Opinion Is Based on Reliable Methodology.

Plaintiffs object to Dr. Zaslau’s observation that mechanical-cut mesh does not rope when it is pulled with the plastic sheath over it. Plaintiffs say that this “is nothing more than the same sort of inadmissible ‘I have not seen it’ testimony that he offers regarding particle loss.” Pls.’ Mem. at 7. However, Dr. Zaslau basis this opinion on reliable *ex vivo* experiments and *in vivo* observations:

[W]e do different experiments with the mesh *ex vivo*. So when we pull on the mesh by itself, be it mechanically-cut or laser-cut, it’ll rip and tear, and it won’t regain its normal form. And the pore size will certainly be distorted. But, interestingly, when we do the same thing with the plastic sheath over it, we can’t move the mesh despite how hard we pull. We’ve actually even looked with an operative telescope. We’ve actually even looked with an operative telescope at patients that we finished doing the TVT on to see if there is any evidence of fiber loss or any change in what I think the mesh should look like, and I’ve never seen any.

Mot. Ex. C, Zaslau 3/17/16 Dep. Tr. 102:9–21. Such experimentation and personal observations are reliable under *Daubert*. *See, e.g., Bullock v. Daimler Trucks N. Am., LLC*, 819 F. Supp. 2d 1172, 1177 (D. Colo. 2011) (“An out-of-court experiment may be offered by an expert at trial in order to illustrate or demonstrate principles used to form an expert opinion.” (citing *Pandit v. Am. Honda Motor Co., Inc.*, 82 F.3d 376, 381–82 (10th Cir. 1996))); *see also Cummins v. Lyle*

Indus., 93 F.3d 362, 370 (7th Cir. 1996) (“Indeed, . . . we acknowledged that ‘there may be a situation in which personal experiments or observations meet the requirements of *Daubert*.’”).

Contrary to Plaintiffs’ assertion that Dr. Zaslau’s “observations cannot be confirmed, and his opinions cannot be contradicted or tested,” Pls.’s Mem. at 7, Dr. Zaslau’s experiment can be easily reproduced (and potentially refuted) by any expert with a sample of mesh and plastic sheathing. Further, Dr. Zaslau’s experimental setup was reliable, as it simulated what the mesh would undergo during the TVT/TVT-O procedure. *See* Mot. Ex B, Zaslau *Hendrix* Report 17–18 (“It is well known that when the plastic tape is pulled quickly or is under tension that the mesh can shear. . . . Thus, the sheath over the mesh, when used according to the manufacturer’s suggestion via video can easily be removed and this potential complication eliminated.”). Accordingly, Dr. Zaslau should be able to offer opinions based on his personal testing and observations of mesh placement using a sheath.

III. Dr. Zaslau’s Opinions About Degradation Are Neither Inconsistent nor Unreliable

Plaintiffs attempt to undercut the reliability of Dr. Zaslau’s degradation opinions based on a series of out-of-context quotes from his deposition. A review of his reports and his deposition transcript makes it clear that Dr. Zaslau’s opinion is that while mesh may theoretically degrade, this degradation is not clinically significant. *See* Resp. Ex. A, Zaslau *Guinn* Report at 26 (opining that “there are no reliable scientific studies evaluating the TVT or TVT-O that have demonstrated any clinical significance to alleged . . . degradation My clinical experience is consistent with the peer-reviewed level 1 clinical evidence in that there is no causal link of TVT-O to cancer or any other complication attributed to particle loss or degradation.”); Mot. Ex. C, Zaslau 3/17/16 Dep. Tr. 126:11–14 (opining that degradation of mesh “has no clinical relevance”). Plaintiffs’ attack on Dr. Zaslau’s degradation opinion is therefore a straw man. Dr.

Zaslau is not offering the opinion that polypropylene degradation cannot occur; he's only opining that if it does occur, it is not clinically significant.

Plaintiffs also attack Dr. Zaslau's qualifications to offer degradation opinions on the grounds that he does not know about the chemical processes of degradation and did not test mesh explants for degradation. However, this Court has previously found urologists qualified to offer opinions about the clinical impact of degradation, despite a lack of polymer science background or degradation testing. For example, in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691 (S.D. W. Va. 2014), plaintiffs challenged the degradation opinions of Ethicon's expert urologist, Dr. Pramudji, on the grounds that Dr. Pramudji did not have adequate experience on the "chemical properties" of mesh. *Id.* at 726. The Court disagreed, finding Dr. Pramudji qualified to offer such opinions based on her personal experience implanting more than 1500 mesh implants, performing 60 to 80 mesh revisions or removals, and examining explanted meshes. *Id.* The Court accordingly found that Dr. Pramudji was qualified to offer the opinion that she has not observed mesh degradation in her clinical practice. *Id.* at 727.

Similarly, Dr. Zaslau is board-certified in female pelvic medicine and reconstructive surgery, also known as urogynecology, and has performed hundreds of TVT and TVT-O implants. Mot. Ex. A, Zaslau *Hendrix* Report 3–4. He and his partner have removed approximately 200 meshes in their medical practice. Mot. Ex. C, Zaslau 3/17/16 Dep. Tr., 48:8–23. He, like Dr. Pramudji, is qualified to offer degradation opinions based on his personal clinical experience. Further, Dr. Zaslau has also reviewed peer-reviewed medical literature and studies in reaching his degradation opinions. *See* Resp. Ex. A, Zaslau *Guinn* Report at 26 (opining that "there are no reliable scientific studies evaluating the TVT or TVT-O that have demonstrated any clinical significance to alleged . . . degradation My clinical experience is

consistent with the peer-reviewed level 1 clinical evidence in that there is no causal link of TVT-O to cancer or any other complication attributed to particle loss or degradation.”). Accordingly, Dr. Zaslau is qualified, based on his personal experience and literature review, to render his opinion that the alleged degradation of Prolene mesh is not clinically significant.

IV. Dr. Zaslau’s Long-Term Pain Opinions Is Supported by His Personal Observations and His Review of Medical Literature.

Plaintiffs challenge Dr. Zaslau’s long-term pain opinions solely based on his failure to identify, at his deposition, a specific study supporting his opinions. However, this contention is wrong, as Dr. Zaslau identified a meta-analysis of medium-term and long-term studies on midurethral slings. Mot. Ex. C, Zaslau 3/17/16 Dep. Tr. 74:5–22; *see also* Resp. Ex. C, Tommaselli, et al., *Medium-term and long-term outcomes following placement of midurethral slings for stress urinary incontinence: a systematic review and metaanalysis*, Int Urogynecol J. 2015 Sep;26(9):1253-68 (reporting results for pain-related complications from studies with follow up of at least 3 years and 5 years for transobturator and retropubic midurethral slings, respectively).

Further, Dr. Zaslau’s inability to recall specific studies reporting on long-term pain does not render his opinions unreliable. *See Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 559 (S.D. W. Va. 2014) (noting that expert’s “failure to recall which articles supported his opinion as to safety is an insufficient reason to find his methodology unreliable” because expert had “extensive experience, . . . had authored peer-reviewed articles on this subject . . . , and considered scientific literature in forming his opinions as evidenced by his relied upon list”). Instead, Dr. Zaslau’s opinion is based both on his 15-plus years of clinical experience using TVT and TVT-O and his review of peer-reviewed medical literature, including several long-term studies. *See generally* Resp. Ex. D, Zaslau Reliance List (listing several long-term studies on

TVT or TVT-O). Accordingly, Dr. Zaslau's opinions on long-term pain are reliable under *Daubert*.

V. Dr. Zaslau Does Not Intend to Offer Opinions About Reasons Why Women May Want Their Mesh Removed.

Plaintiffs object to Dr. Zaslau's testimony about reasons women may want their mesh removed. However, this opinion is not in Dr. Zaslau's reports, and Dr. Zaslau does not intend to offer such opinions. Plaintiffs' Motion on this issue should therefore be denied as moot.

Respectfully submitted,

/s/ Christy D. Jones

Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523
christy.jones@butlersnow.com

/s/ David B. Thomas

David B. Thomas (W.Va. Bar #3731)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
(304) 414-1807
dthomas@tcspllc.com

COUNSEL FOR DEFENDANTS
ETHICON, INC. AND JOHNSON & JOHNSON

CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones
Christy D. Jones